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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/973,853      | 10/10/2001  | Neville J. Anthony   | 20757Y              | 7109             |

210 7590 07/26/2004

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EXAMINER

COLEMAN, BRENDA LIBBY

|          |              |
|----------|--------------|
| ART UNIT | PAPER NUMBER |
|----------|--------------|

1624

DATE MAILED: 07/26/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

|                              |                                      |                                       |  |
|------------------------------|--------------------------------------|---------------------------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b><br>09/973,853 | <b>Applicant(s)</b><br>ANTHONY ET AL. |  |
|                              | <b>Examiner</b><br>Brenda Coleman    | <b>Art Unit</b><br>1624               |  |

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 06 May 2004.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1 and 3-37 is/are pending in the application.
- 4a) Of the above claim(s) 16-20, 28, 29 and 33-36 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 3-15, 21-27, 30-32 and 37 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>2/18/04, 3/18/04, 5/6/04, and 5/11/04</u> | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

Claims 1 and 3-37 are pending in the application.

This action is in response to applicant's amendment filed May 6, 2004. Claims 1, 4, 7-9 and 11 have been amended.

### ***Election/Restrictions***

1. Claims 16-20, 28, 29 and 33-36 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 13.

### ***Response to Amendment***

Applicant's amendments and arguments filed May 6, 2004 have been fully considered with the following effect:

2. With regards to the 35 U.S.C. § 112, first paragraph rejection of claims 25-27 and 30-32 labeled paragraph number 2) in the last office action, the applicant's amendments and remarks have been fully considered but they are not persuasive. The applicants stated that the specification discloses that representative compounds of the invention inhibit HIV replication and describes how to use the compounds of the invention by providing a detailed description of suitable forms, pharmaceutical compositions and their preparation, routes of administration, and dosages. The applicants also stated that using this description, optionally in combination with know how available in the art, the person of ordinary skill can without undue experimentation prepare and administer a compound of the invention in a suitable carrier and in the appropriate dosage form and

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dosage amount to a subject in order to treat HIV infection and AIDS. However, with respect to claims 26 and 30 it is not the treatment of HIV infection and AIDS but the inhibition of HIV integrase that is being claimed. The applicants stated that none of the rejected claims is directed to the inhibition of HIV integrase, so the mode of action of the claimed compounds is not pertinent, which is not so. Hence the 35 U.S.C. § 112, first paragraph rejection is herein maintained with respect to claims 26 and 30.

Claims 26 and 30 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention, for reasons of record and stated above.

3. With regards to the 35 U.S.C. § 112, first paragraph rejection of claims 1, 3-13, 25-27 and 32 labeled paragraph number 10) in the last office action, the applicant's amendments and remarks have been fully considered but they are not persuasive. The applicants stated that claim 1 has been amended to replace " $-H(R^a)R^t$ " in the definition of  $R^k$  with " $-N(H)R^t$  or  $-N(C_{1-6} \text{ alkyl})R^t$ " and that claim 1 as originally filed provides express support for  $-N(C_{1-6} \text{ alkyl})R^t$  and support for  $-N(H)R^t$  can be found, for example, in claim 4 as originally filed, which recites  $-N(R^a)R^t$  (where  $R^a$  is H or  $C_{1-4}$  alkyl) as a substituent of  $R^k$ . However, the definition of  $R^k$  in claim 4 is part of a sub-genus of formula (II), with specific variables, not the description of the genus of Formula I. Additionally, recent case law *Tronzo v. Biomet* 47 USPQ2d 1829 states that a species in a prior application does not provide written description to a generic claim.

Claims 1, 3-13, 25-27 and 32 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention, for reasons of record and stated above.

4. With regards to the provisional obviousness-type double patenting rejection as being unpatentable over copending Application No. 10/399,083, Attorney Docket No. 20950Y, 10/398,929 and 10/218,537 labeled paragraphs 5, 6, 7 and 8 in the last office action, the applicant's remarks have been fully considered but they are not persuasive. The applicant's stated that when the only rejection remaining is a provisional double patenting rejection, the Examiner should withdraw the rejection and allow the application to issue as a patent. However, this is not the only issue remaining.

Claims 1, 3-15, 21-27, 30-32 and 37 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims of copending Application No. 10/399,083, for reasons of record and stated above.

5. Claims 1, 3-15, 21-27, 30-32 and 37 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims of copending Application No. 10/486,535, for reasons of record and stated above.

6. Claims 1, 3-15, 21-27, 30-32 and 37 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over

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claims of copending Application No. 10/398,929, for reasons of record and stated above.

7. Claims 1, 3-15, 21-27, 30-32 and 37 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims of copending Application No. 10/218,573, for reasons of record and stated above.

8. With regards to the 35 U.S.C. § 112, second paragraph rejection labeled paragraph 11) of the last office action, the applicant's amendments and remarks have been fully considered but they are not persuasive. The applicants failed to comment on the 35 U.S.C. § 112, second paragraph rejection of claim 11 which is directed to the lack of antecedent basis for  $-N(R^a)-C(=O)-(CH_2)_{1-2}-C(=O)-N(R^a)_2$  in the definition of  $R^k$ .

Claim 11 is rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, for reasons of record and stated above.

### ***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the

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shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brenda Coleman whose telephone number is 571-272-0665. The examiner can normally be reached on 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mukund Shah can be reached on 571-272-0674. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

*Brenda Coleman*

Brenda Coleman  
Primary Examiner Art Unit 1624  
July 20, 2004